FORM PTO-1390

U.S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE ATTORNEY'S DOCKET NUMBER

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. §371

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U.S APPLICATION NO (If known, see 37 CFR §1.5)

09/720136

INTERNATIONAL APPLICATION NO

INTERNATIONAL FILING DATE

PCT/US99/13894

22 JUNE 1999

PRIORITY DATE CLAIMED

23 JUNE 1998

TITLE OF INVENTION

USE OF OILS HAVING A HIGH LAURIC ACID CONTENT AS AN ANIMAL FEED

APPLICANT(S) FOR DO/EO/US

TETER, Beverly B.

Applicant nerewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information
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- This is a FIRST submission of items concerning a filing under 35 U.S.C. §371.
- 2.

 This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. §371.
- 3.
 This express request to begin national examination procedures (35 U.S.C. §371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. §371(b) and PCT Articles 22 and 39(1).
- 4. A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
- A copy of the International Application as filed (35 U.S.C. §371(c)(2))
 - a. \square is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. has been transmitted by the International Bureau.
 - is not required, as the application was filed in the United States Receiving Office (RO/US).
 - A translation of the International Application into English (35 U.S.C. §371(c)(2)).
 - Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. §371(c)(3))
 - a.

 are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. have been transmitted by the International Bureau.
 - c. \square have not been made; however, the time limit for making such amendments has NOT expired.
 - d.
 have not been made and will not be made.
- A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. §371(c)(3)).
- ☐ An oath or declaration of the inventor(s) (35 U.S.C. §371(c)(4)).
- 0. □ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. §371(c)(5)).

Items 11. to 16. below concern document(s) or information included:

- 11.

 An Information Disclosure Statement under 37 C.F.R. §§1.97 and 1.98.
- 12.

 An assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. §§3.28 and 3.31 is included.
- A FIRST preliminary amendment.
 - ☐ A SECOND or SUBSEQUENT preliminary amendment.
- 14. A substitute specification.
- 15. ☐ A change of power of attorney and/or address letter.
- 16. ☐ Other items or information:



528 Rec'd PCT/PTO 21 DEC 2000

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(November 1998)

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IN THE UNITED STATES DESIGNATED/ELECTED OFFICE

International Application No.

PCT/US99/13894

International Filing Date

22 JUNE 1999

Priority Date(s) Claimed

23 JUNE 1998

Applicant(s) (DO/EO/US)

TETER, Beverly B.

Title: USE OF OILS HAVING A HIGH LAURIC ACID CONTENT AS AN ANIMAL

FEED

PRELIMINARY AMENDMENT

Commissioner for Patents Washington, D.C. 20231

SIR:

Although amendments were made during the International phase under Article 19, applicants request that examination in the U.S. National Phase be based on the application as filed.

Respectfully submitted

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Attorney for Applicants

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RJT:jmm

WO 99/66804

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USE OILS HAVING A HIGH LAURIC ACID CONTENT AS AN ANIMAL FEED

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BACKGROUND OF THE INVENTION

of antibiotics dispensed in the United States are administered in sub-therapeutic doses

to promote weight gain in apparently healthy livestock. Increasingly, the use of

antibiotics at sub-therapeutic levels in livestock has been implicated in the

The invention relates to the field of livestock production. About one quarter

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development of antibiotic resistance in bacteria, including human pathogenic bacteria

and foodborne bacteria. J. Raloff, 1998, Science News 154:39; J. Raloff, 1999,

Science News 155:356. Additionally, antibiotic residues in meat products is also of

concern. Therefore, effective methods and compositions for reducing the use of

antibiotics in the agricultural sector are needed.

SUMMARY OF THE INVENTION

In accordance with the current invention, methods and compositions for

reducing or eliminating the use of antibiotics to promote the growth of animals have

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been discovered. The methods and compositions relate to the use of an anti-microbial fatty acid component as part of the animal feed, either combined with the feed or administered separately as a feed supplement. The methods and compositions of the invention allow for the elimination or reduction of the use of antibiotics as growth promoters in animals. This reduction or elimination is important for several reasons, including but not limited to the following: (1) use of antibiotics as growth promoters in animals is known to contribute to the development of antibiotic resistance in microorganisms, particularly foodborne microorganisms; (2) use of antibiotics as growth promoters in animals results in antibiotic residue in animal tissue used for human food; and (3) use of antibiotics as growth promoters contributes to the introduction into the ecosystem of mutant, antibiotic resistant forms of common organisms, through the exposure of microorganisms to antibiotics in the animal and to antibiotics excreted in fecal matter. Therefore, in allowing for the elimination or

reduction in the use of antibiotics in livestock management and in the management of

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other production animals, the methods and compositions of the invention address a pressing problem in the agricultural sector.

One aspect of invention is a method for reducing the antibiotic content of animal feed comprising feeding the animals an anti-microbial fatty acid component as part of the animal feed, either combined with the feed or administered separately as a feed supplement. Animal feed, as used herein, includes all solid or semi-solid feeds, as well as liquid feed such as milk-replacers. The anti-microbial fatty acid component may comprise at least one fatty acid or glyceryl ester of a fatty acid, or a derivative thereof, which has an anti-microbial activity and which is suitable for use as animal feed. The anti-microbial fatty acid component may also comprise at least one precursor to a fatty acid or glyceryl ester of a fatty acid, or derivative thereof, having anti-microbial activity, provided the precursor is suitable for use as animal feed and is convertible to a form that is active as an anti-microbial by the animal's digestive process. Preferred anti-microbial fatty acid components, either provided directly to the animal or in precursor form, are those described in Kabara et al. (U.S. Pat. No. 4,002,775), Iwasaki et al. (4,961,934), Olund et al. (U.S. Patent No. 5,550,145), and Hayashi (U.S. Patent No. 5,462,967). For example, preferred anti-microbial fatty acid components, either provided directly to the animal or in precursor form, are lauric acid, monolaurin, other medium chain length fatty acids (C6 to C14) and glyceryl monoesters thereof, and palmitoleic (C16:1) and oleic acid (C18:1), and glyceryl monoesters thereof. Preferred precursor forms of fatty acids or glyceryl monoesters of fatty acids are diglycerides and triglycerides having lauroyl substituents.

Anti-microbial, as used herein, refers to a compound or composition having measurable activity against any of bacteria, fungi, viruses, protozoa, etc., or combinations thereof. Assays for describing such activity of fatty acid components are well known in the art and are described for example in Fletcher et al., 1985, Effect of monoglycerides on *Mycoplasma pneumonia* growth, in *The Pharmacological Effects of Lipids II* (J.J. Kabara ed., The American Oil Chemists' Society, Champaign, Illinois); Schemmel and Kabara, 1985, Fatty Acids, Monoglycerides and Sucrose Esters as Anticaries Agents Review, in *The Pharmacological Effects of Lipids II* (J.J. Kabara ed., The American Oil Chemists' Society, Champaign, Illinois);

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Kabara, 1985, Inhibition of Staphylococcus aureus in a model sausage system by monoglycerides, in The Pharmacological Effects of Lipids II (J.J. Kabara ed., The American Oil Chemists' Society, Champaign, Illinois); Sands et al., 1978, Antiviral effects of fatty acids and derivatives; lipid-containing bacteriophages as a model system, in The Pharmacological Effects of Lipids I (J.J. Kabara ed., The American Oil Chemists' Society, Champaign, Illinois); Li and Kabara, 1978, Effects of lauricidin on Fomes annosus and Phellinus weirii, in The Pharmacological Effects of Lipids I (J.J. Kabara ed., The American Oil Chemists' Society, Champaign, Illinois); Kabara, 1978, Fatty acids and derivatives as antibiotic agents; A review, in The Pharmacological Effects of Lipids I (J.J. Kabara ed., The American Oil Chemists' Society, Champaign, Illinois);

A preferred anti-microbial fatty acid component contains lauric acid or monolaurin or contains precursors for lauric acid or monolaurin. A particulary preferred anti-microbial fatty acid component comprises natural oils wherein a high percentage of fatty acid substituents on the triglycerides, diglycerides and monoglycerides are lauroyl substituents (referred to herein as "high lauric acid oils"). High lauric acid oils preferably comprise at least about 20% lauric acid as acylated fatty acids in the triglyceride, more preferably at least about 40%, and most preferably at least about 50%. Such natural oils include, but are not limited to coconut oil, rapeseed oil, palm kernel oil, murumuru tallow, and tucum oil. As used herein natural oils means any oil derived from plant or animal material including, but not limited to, oils that are derived from plants that have been genetically modified either through traditional breeding or through genetic engineering techniques. As one example, canola oil, rapeseed oil or soybean oil, derived from plants that have been genetically modified to have a high lauric acid content may be employed. Such an oil is available, for example, under the tradename Laurical® from Calgene Inc., Davis, California. When high lauric acid oils are ingested by an animal, the digestive enzymes release lauric acid and monolaurin. The lauric acid and monolaurin are then either absorbed through the intestinal wall into the blood stream or remain in the digestive tract. Therefore, the lauric acid or monolaurin can exert an anti-microbial effect systemically within the animal or within the digestive tract.

In one aspect of the invention, high lauric acid oil will be employed as part of the feed or as a feed supplement such that lauric acid will preferably comprise about 0.5% to about 10% of the animal feed, more preferably about 2% to about 7%, and most preferably about 3% to about 5% of the feed. For high lauric acid oils which contain approximately 50% lauric acid as acylated fatty acids, such as coconut oil or palm kernel oil, the feed will typically comprise about 1% to about 20% high lauric acid oil, preferably about 4% to about 14%, and more preferably about 6% to about 10%.

Animals, as used herein, includes, but is not limited to, farm livestock, pets, and any animals produced for human consumption. Preferred animals include poultry (chickens, turkey, ducks, ostrich, emu, quail etc.), fish, pigs, lambs, veal calves, dairy calves, beef calves, and any other monogastric livestock. Preferred animals are production animals. Production animals, as used herein, are animals which produce food for human consumption. Animals, as used herein, also refers to ruminant animals. However, for ruminant animals, it is desirable that the fatty acid component be rumen protected, so as not to exert deleterious effects on the bacteria in the rumen. Methods of rumen protection are described, for example, in Vinci et al. (U.S. Patent No. 5,182,126), Cummings et al. (U.S. Patent No. 5,250,307), LaJoie et al. (U.S. Patent No. 5,874,102), which are hereby incorporated by reference.

In one aspect of the invention, a high lauric acid oil is added to the feed of poultry, particularly, either as feed or as a feed supplement, to promote the health of the chickens or to prevent bacterial contamination of poultry products, including contamination by *Salmonella typhimurium*. Poultry products include any part of the bird that is used for human consumption, as well as egg products. Preferred poultry includes chickens and turkeys. According the invention, sufficient high lauric acid oil will be included in the diet of the chickens such that lauric acid will preferably comprise about 0.5 % to about 10 % of the diet, more preferably about 2 % to about 7 %, and most preferably about 3 % to about 5 %.

According to the invention, methods and compositions for achieving a high feed efficiency with reduced amounts of antibiotics are described. Feed efficiency, as used herein and as generally known in the art, refers to the following ratio: weight

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gain of the animal/weight of food ingested. In one aspect of the invention, preferably at least 85%, and more preferably at least 90%, and most preferably at least 95%, of the optimal feed efficiency achievable with any particular diet and antibiotic supplement (optimal antibiotic supplement), can be achieved with less than 50% the optimal antibiotic supplement by the supplementation of the diet with lauric acid. In another aspect of the invention, preferably at least 85%, more preferably at least 90%, and most preferably at least 95%, of the maximal feed efficiency achievable with any particular diet and the maximum antibiotic supplement allowable under Title 21 of the Code of Federal Regulations, Section 558 (allowable antibiotic supplement), can be achieved with less than 50% the allowable antibiotic supplement by the supplementation of the diet with lauric acid. It is of course recognized that the allowable antibiotic supplement for increasing feed efficiency will depend on the type of animal and the use of the animal. For example, 21 CFR § 558 may specify a different allowable antibiotic supplement for broiling chickens and laying chickens. Title 21 of the Code of Federal Regulations, Section 558, entitled "New Animal Drugs for Use in Animal Feed", is hereby incorporated herein by reference.

It is of course recognized by one of skill in the art that the lauric acid supplement to the diet, typically in the form of a natural oil, may replace other fats in the diet. A high feed efficiency (e.g. ≥ 85%) is preferably achieved with less than about 50% of the optimal antibiotic supplement, more preferably with less than about 40% of the optimal antibiotic supplement, and most preferably less than about 30% of the optimal antibiotic supplement. Additionally, a high feed efficiency (e.g. ≥ 85%) is preferably achieved with less than about 50% of the allowable antibiotic supplement, more preferably with less than about 40% of the allowable antibiotic supplement, and most preferably less than about 30% of the allowable antibiotic supplement.

In another aspect of the invention, high feed efficiency is preferably achieved with less than about 50% of the usual antibiotic supplement for a particular application, more preferably with less than about 40%, and most preferably with less than about 30%. The usual antibiotic supplement for a particular application can be readily determined by one of skill in the art.

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According to the invention, methods and compositions for achieving control of Salmonella typhimurium in poultry with reduced amounts of antibiotics are described. Control of Salmonella typhimurium, as used herein, is determined by assaying for the presence of Salmonella typhimurium in the chickens, using techniques that are well know in the art. As is well known in the art, assays can be conducted, for example, on fecal droppings from the animals or through the culture of intestinal bacteria or bacteria present in the oviduct in the animals. Assays of oviduct bacteria would be important for determining the effects of methods and compositions of the invention for reducing the risk of contamination of the interior of eggs with Salmonella typhimurium. In one aspect of the invention at least 85%, preferably at least 90%, and more preferably at least 95%, of the optimal Salmonella typhimurium control achievable with any particular diet and antibiotic supplement (optimal antibiotic supplement for control of Salmonella typhimurium), can be achieved with less than 50% the optimal antibiotic supplement for control of Salmonella typhimurium by the supplementation of the diet with lauric acid. In another aspect of the invention at least 85%, preferably at least 90%, and more preferably at least 95%, of the maximum Salmonella typhimurium control achievable with any particular diet and the maximum antibiotic supplement allowable under Title 21 of the Code of Federal Regulations, Section 558 (allowable antibiotic supplement for control of Salmonella typhimurium) can be achieved with less than 50% the allowable antibiotic supplement for control of Salmonella typhimurium by the supplementation of the diet with lauric acid. It is of course recognized that the allowable antibiotic supplement for controlling Salmonella typhimurium will depend on the type of animal and the use of the animal. For example, 21 CFR § 558 may specify a different allowable antibiotic supplement for broiling chickens and laying chickens.

Control of Salmonella typhimurium (e.g. \geq 85%) is preferably achieved with less than about 50% of the optimal antibiotic supplement for control of Salmonella typhimurium, more preferably with less than about 40%, and most preferably less than about 30%. Additionally, control of Salmonella typhimurium (e.g. \geq 85%) is preferably achieved with less than about 50% of the allowable antibiotic supplement

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for control of *Salmonella typhimurium*, more preferably with less than about 40%, and most preferably less than about 30%.

In another aspect of the invention, control of *Salmonella typhimurium* is preferably achieved with less than about 50% of the usual antibiotic supplement for a particular application, more preferably with less than about 40%, and most preferably with less than about 30%. The usual antibiotic supplement for a particular application can be readily determined by one of skill in the art.

Also contemplated as part of this invention are animal feed compositions comprising a lauric acid component and a minimal or reduced antibiotic level as described above.

Without further elaboration, it is believed that one skilled in the art can, using the preceding description, utilize the present invention to its fullest extent. The following preferred specific embodiments are, therefore, to be construed as merely illustrative, and not limitative of the remainder of the disclosure.

EXAMPLES_

In the following examples, all parts and percentages are by weight unless otherwise indicated.

Example 1 - Determination of optimal type and amount of a fatty acid component.

For any given animal type the optimal type and amount of fatty acid component for the diet can be determined using knowledge and skills that are well known in the art.

However, as a specific example, the optimal protocol for reducing or eliminating antibiotics in chicken feed through the use of coconut oil as a feed supplement would be determined as follows, for a particular breed of chicken. Three groups of chickens are evaluated. All groups are fed normal or experimental starter diets, which are switched to the experimental or normal growth and finishing diets at the proper ages. The starter diets are fed to the chickens for days 0-15 after hatching and consist of about 26% crude protein and 6% fat. The growth diet (days 15-32) is

adjusted to decrease the protein content to about 20% and to increase the fat content to about 7%. A finishing/withdrawal diet is fed to the chicks for days 33-42 and this diet consists of the growth diet with, with exception that antibiotics are eliminated from the diet for those groups receiving antibiotics.

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A Ross x Ross Hiyield strain of chicken (broiler chickens) are used for the study. The birds are housed with litter for the first 15 to 18 days and then transferred to pens. The experiment involves six birds per group, three assortment groups (one control group and two treatment groups), and eight replicates, for a total of 144 birds. At the end of the starter period (day 15), two birds from each group will be sacrificed for assay purposes.

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The first group, a control group, is fed the normal diet, including the antibiotic supplements which are ordinarily a part of the normal diet. The second group is fed the normal diet, with no antibiotics, and with some of the fat in the diet replaced with coconut oil, so that lauric acid would comprise about 3% by weight of the diet. The coconut oil can be applied to the feed pellets after extrusion in amounts appropriate for the diet formulation. Since coconut oil contains about 50% lauric acid, addition of coconut oil to the diet to comprise about 6% would yield a diet with 3% lauric acid. For Ross x Ross Hiyield chickens, the diet would provide about 3.6 g/day of lauric acid. The third group would receive the lauric acid supplemented diet and one half of the usual amount of antibiotics. For example, typical antibiotics employed for growth promotion in chickens include the following: narasin/nicarbazin (tradename Maxiban/BMD), there is a five day withdrawal period before the birds can be killed for food; chlortetracycline with salinomycin, typically employed in an amount of 0.05 to 0.1 lb/ton of feed, there is one day withdrawal period before the birds can be killed for food; monensin (tradename Coban), typically employed at a rate of 0.1 lb/ton of feed; and Zn Bacitracin, typically employed in an amount of 0.4 lb/ton, there is a five day withdrawal period before the birds can be killed for food.

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The growth parameters of the chicks are monitored twice a week. Monitoring includes measurements of body weight, length, general health, and leg and foot development, etc. At the end of the experiment, when the birds reach market weight, the birds are sacrificed for assay purposes. The chickens sacrificed at day 15 and the

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market weight chickens are assayed as follows: the intestinal contents are cultured for *Salmonella*, *E. coli*, and other coliform bacteria; fecal cultures are taken; bone mineralization is determined; intestinal brush border enzymes are analyzed; samples of the jejunum are analyzed by electron microscope examination; and intestinal lymphocyte function is analyzed.

The optimal combination of the fatty acid component with a particular antibiotic. or combination of antibiotics, may also be determined. The fatty acid component is combined with 0%, 20%, 30%, 40,% and 50% of the usual antibiotic supplement and the chickens are evaluated as described above to determine the minimal level of antibiotic which, in combination with the fatty acid component, yields optimal growth of the chickens.

The preceding examples can be repeated with similar success by substituting the generically or specifically described reactants and/or operating conditions of this invention for those used in the preceding examples.

Without further elaboration, it is believed that one skilled in the art can, using the preceding description, utilize the present invention to its fullest extent. The preceding preferred specific embodiments are, therefore, to be construed as merely illustrative, and not limitative of the remainder of the disclosure in any way whatsoever.

The entire disclosure of all patent applications, patents, and publications cited herein are hereby incorporated by reference.

From the foregoing description, one skilled in the art can easily ascertain the essential characteristics of this invention and, without departing from the spirit and scope thereof, can make various changes and modifications of the invention to adapt it to various uses and conditions.

AMENDED CLAIMS

[received by the International Bureau on 10 november 1999 (10.11.99); original claims 1-25 replaced by amended claims 1-21 (3 pages)]

WHAT IS CLAIMED IS:

- 1. A method for promoting animal health with animal feed having reduced antibiotic content comprising
- providing an animal feed to animals,
 wherein the animal feed comprises an anti-bacterial fatty acid component,

wherein the anti-bacterial fatty acid component is a high lauric acid natural oil, or a derivative thereof having high lauric acid content.

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- 2. A. method according to claim 1, wherein the high lauric acid oil is coconut oil, palm kernel oil, or high lauric acid rapeseed oil.
- 3. A method according to claim 1, wherein lauric acid in the high lauric acid oil comprises from 0.5 % to 10 % of the animal feed.
 - 4. A method according to claim 1, wherein the animal feed is essentially free of other antibiotics.
- 5. A method according to claim 1, wherein antibiotics present in the animal feed comprise less than 50% of the optimal antibiotic supplement.
 - 6. A method according to claim 1, wherein antibiotics present in the animal feed comprise less than 50% of the maximal antibiotic supplement.

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- 7. A method according to claim 1, wherein the animals are chickens, turkeys, lambs or veal calves produced for human consumption.
- 8. A method according to claim 7, wherein the animal feed comprises less than 50% of the optimal antibiotic supplement for controlling Salmonella typhimurium.

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- 9. A method according to claim 7, wherein the animal feed comprises less than 50% of the optimal antibiotic supplement for controlling Salmonella typhimurium.
- 10. An animal feed composition comprising

an anti-bacterial fatty acid component,

wherein the anti-bacterial fatty acid component is a high lauric acid natural oil, or a derivative thereof having high lauric acid content..

- 11. An animal feed composition according to claim 10, wherein the high lauric acid oil is coconut oil, palm kernel oil, or a high lauric acid rapeseed oil.
- 12. An animal feed composition according to claim 10, wherein lauric acid in the high lauric acid oil, or derivative thereof, comprises 0.5 % to 10 % of the animal feed.
- 13. An animal feed composition according to claim 10, wherein the animal feed composition is essentially free of other antibiotics.
 - 14. An animal feed composition according to claim 10, wherein antibiotics in the animal feed comprise less than 50% of an optimal antibiotic supplement.
 - 15. An animal feed composition according to claim 10, wherein antibiotics in the animal feed comprise less than 50% of a maximal antibiotic supplement.
- 16. An animal feed composition according to claim 10, wherein antibiotics in the
 animal feed comprise less than 50% of an optimal antibiotic supplement for controlling Salmonella typhimurium.
 - 17. An animal feed composition according to claim 10, wherein antibiotics in the animal feed comprise less than 50% of an allowable antibiotic supplement for controlling Salmonella typhimurium.

- 18. An animal feed composition according to claim 10, wherein the feed composition is feed for chickens, turkeys, lambs or veal calves produced for human consumption.
- 19. A method for reducing the antibiotic content of an animal feed which contains antibiotics comprising

replacing all or a portion of the antibiotics in the animal feed with an antibacterial fatty acid component to obtain modified feed, wherein the antibiotic effect of the animal feed in enhancing feed efficiency is maintained in the modified feed.

- 20. A method according to claim 19, wherein less than 50% of an optimal antibiotic supplement is present in the modified feed.
 - 21. A method according to claim 19, wherein less than 50% of an allowable antibiotic supplement is present in the modified feed.

DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

USE OF OILS HAVING A HIGH LAURIC ACID CONTENT AS AN ANIMAL FEED

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□ is attached here	to
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■ was filed on ____22 JUNE 1999 ___ as United States Application Number or PCT International Application Number ____PCT/US99/13894 ___ and (if applicable) was amended on _____

I hereby authorize our attorneys to insert the serial number assigned to this application.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR §1.56.

I hereby claim foreign priority benefits under 35 U.S.C. §119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or PCT International application having a filing date before that of the application on which priority is claimed.

19	PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 USC §119							
	APPLICATION NO.	COUNTRY	DAY/MONTH/YEAR FILED	PRIORITY CLAIMED				
the same	60/090,303	US	23/06/1998	YES				

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below.

	PROVISIONAL APPLICATION(S) UNDER 35 U.S.C. §119(e)					
APF	PLICATION NUMBER	FILING DATE				

I hereby claim the benefit under 35 U.S.C. §120 of any United States application, or §365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. §112.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR §1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application.

PRIOR U.S./PCT INTERNATIONAL APPLICATION(S) DESIGNATED FOR BENEFIT UNDER 37 U.S.C. §120						
APPLICATION NO. FILING DATE		STATUS — PATENTED, PENDING, ABANDONED				

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith: I. William Millen (19,544); John L. White (17,746); Anthony J. Zelano (27,969); Alan E.J. Branigan (20,565); John R. Moses (24,983); Harry B. Shubin (32,004); Brion P. Heaney (32,542); Richard J. Traverso (30,595); John A. Sopp (33,103); Richard M. Lebovitz (37,067); John H. Thomas (33,460); Catherine M. Joyce (40,668); Nancy J. Axelrod (44,014); James T. Moore (35,619); James E. Ruland (40,921) and Jennifer J. Branigan (37,432)

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Residence

Post Office Address

and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon. Full Name of sole or first inventor (given name, family name) Signature March 9, 281/ Residence College Park, MD US Post Office Address 3731 Marlborough Way, College Park, MD, 20742 Full Name of additional joint inventor (given name, family name) Date Signature Citizenship Residence Post Office Address Full Name of additional joint inventor (given name, family name) Date Signature Ţ Citizenship Residence . . IJ Post Office Address Full Name of additional joint inventor (given name, family name) Ш Date Signature <u>I</u> Citizenship Residence Post Office Address Full Name of additional joint inventor (given name, family name) Œ. Date Signature

Citizenship

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements

Additional joint inventors are named on separately numbered sheets attached hereto.